Periodontal-Type Measurements Associated With Hydroxyapatite-Coated and Non–HA-Coated Implants: Uncovering to 36 Months

Harold F. Morris,*†‡ Shigeru Ochi,*‡ J. Robert Spray,§ and John W. Olson‖

** Dental Implant Clinical Research Group, VA Medical Center, Ann Arbor, MI.*
† Department of Restorative Dentistry, Temple University, School of Dentistry, Philadelphia, PA.
‡ University of Otago, School of Dentistry, Dunedin, New Zealand.
§ Central Arkansas Veterans Healthcare System; University of Arkansas for Medical Sciences, Little Rock, AR.
‖ Department of Periodontics, Endodontics, and Dental Hygiene, University of Louisville School of Dentistry, Louisville, KY.

Background: While the use of hydroxyapatite (HA)-coated endosseous dental implants has gained in popularity over the past 10 years, the short-term and long-term predictability and indications for their use remain highly controversial. Some reports suggest that the HA coating may separate from the substructure, undergo dissolution in tissue fluids, and/or contribute to rapid osseous breakdown around the implant. Other reports, however, relate favorable responses to HA-coated implants, which include rapid bone adaptation to the HA, greater stability at uncovering, and increased coronal bone growth. These contradictions may be related to differences in chemical composition of the HA on the implant surface. Most clinicians and researchers may agree that long-term, independent, scientific clinical studies are needed to compare HA-coated and non–HA-coated (titanium-alloy and CP-titanium) implants under the same conditions. Concerns appear in the literature that HA-coated implants experience greater breakdown because they are more susceptible to bacterial colonization due to their roughness and hydrophilicity. Some studies suggest that specific putative periodontal pathogens may adhere to the HA, thereby predisposing the implant to greater peri-implantitis than that experienced by non-HA implants.

Methods: A total of 32 clinical research centers, located in various geographic regions of the United States, were selected to participate in a comprehensive clinical study. More than 2,900 HA-coated and non-HA implants were randomized as to location within one of three jaw regions—maxillary anterior, mandibular anterior, and mandibular posterior—and followed for 36 months. It can be assumed that in each of these jaw regions, the conditions associated with both implant surface types would be similar enough to permit meaningful comparisons of periodontal-type measurements that have not previously been reported. Periodontal-type measurements (gingiva, plaque, suppuration, and calculus indices; probing depth; attachment levels; recession; and keratinized tissue width) for each aspect of each implant (mesial, facial, distal, and lingual) were recorded at 3, 6, 9, 12, 18, 24, and 36 months following implant uncovering. The implant was considered the experimental unit for analysis using generalized estimating equation and repeated measure methods. Data for the four aspects of each implant, as well as measurements over time, were all clustered in the unit of analysis.

Results: The percentages of implants with zeros recorded for the indices was remarkably similar for both HA-coated and non-HA implants. While statistically significant differences were found for some of the measurements associated with HA-coated and non-HA implants under certain conditions, these differences were too small to be considered clinically significant.

Conclusions: Overall, there was no clinically significant difference between the periodontal-type measurements for HA-coated and non–HA-coated implants followed for a period from 3 through 36 months. The concerns about HA-coated implants being associated with adverse periodontal responses for the HA chemical composition included in this study appear to be unfounded for a period of clinical performance up to 36 months. *Ann Periodontol 2000;5:56-67.*

KEY WORDS

Comparison studies; dental implants; follow-up studies; hydroxyapatite/therapeutic use; periodontal diseases/etiology.

This is U.S. Government-supported research, and there are no restrictions on its use. This paper has been approved for publication by the Dental Implant Clinical Research Group (DICRG), Department of Veterans Affairs. The views expressed in this article are those of the authors and do not reflect the views or policies of the U.S. Department of Veterans Affairs, nor imply endorsement by the U.S. Government.

The first use of hydroxyapatite (HA)-coated endosseous dental implants reported for implant-prostheses was in 1984,[1] and their popularity has increased dramatically. Their use, however, remains controversial. There are reports of unstable HA coatings,[2,3] susceptibility to bacterial infection, and rapid osseous breakdown around the implant site. Biesbrock and Edgerton note that significant long-term advantages over the use of commercially pure (CP) titanium implants have not yet been clearly documented,[4] and the information supporting the use of HA implants tends to be based on largely anecdotal data, and not data from scientific clinical studies. The obstacles that exist which complicate obtaining the information needed are considerable. They include: the large variability in the definitions of survival/success, implant case selection, surgeon's experience, surgical protocols, postoperative regimens, and prosthetic restorations. If not resolved, they make questionable any comparison of clinical performance data for HA-coated and non-HA implants from different clinical studies.

The chemical composition and physical properties of commercial HA coatings may vary widely,[5] which may contribute to the differences reported in the literature. A commercial HA coating for dental implants may contain different percentages of crystalline HA, beta-tricalcium phosphate (β-TCP), and amorphous calcium phosphate, with crystallinity varying between 30% and 66%.[6] Physical properties are largely related to their biochemical calcium phosphate phase,[7] and the dissolution characteristics may well be related to the crystalline HA,[5] while the ratio of HA to β-TCP may impact on favorable bone regeneration.[8]

Of the current information that is related to HA-coated and non-HA implants and available in the dental literature, there exists a lack of detailed comparison of these two implant types under similar conditions. Unfortunately, variations in surgical protocols, surgeon's experience, subjects, restorative procedures, follow-up protocols, and definitions of survival differ widely. An experimental design that contains conditions similar to those found in a "paired comparison" will facilitate ideally the comparison of two implant designs. Differences in the conditions under which the data are gathered alter the recorded outcomes of the studies, making attempts at meta-analysis of little value. In addition to providing meaningful survival data, a study of HA and non-HA implants should compare periodontal-type measurements (gingival, plaque, calculus, and suppuration indices, as well as recession, width of keratinized tissue, attachment levels, and probing depth) during clinical function for a specific period of time. Clinical research that utilizes paired comparisons represents one of the most robust comparisons associated with clinical studies.

The purpose of this study was to compare the gingival, plaque, calculus, and suppuration indices, as well as relative recession, attachment levels, probing depth, and width of keratinized tissues, associated with both HA-coated and non–HA-coated implants, under conditions similar to those found in paired-comparison studies. The data cover a period from 3 months (baseline) to 36 months of post-uncovering follow-up.

MATERIALS AND METHODS

A total of 32 clinical research centers (30 VA medical centers and 2 universities) participated in this ongoing clinical study. The centers are located in various geographic regions across the United States to increase the ability to relate the findings to most dentists and their patients. To facilitate the ability to relate the findings of the study to the majority of dentists, 85 dentists with different training levels and experience were selected for participation from the various regional clinical research centers.

After being selected to participate in the Dental Implant Clinical Research Group (DICRG, U.S. Department of Veterans Affairs) clinical study, each dentist was required to complete an investigator profile form to establish a database of the clinical investigators involved in the study. Investigator information included level of training, number of implants previously placed or restored, and the number of research projects in which the dentist had participated, as well as the number of their scientific papers/oral presentations.

All clinical investigators received training during a 1-week session before beginning the study. The training included calibration for surgical, restorative, and follow-up procedures, as well as the handling of any complications. The data collection instruments/forms were addressed in considerable detail, which included entering sample data on each of the forms.

Subjects were predominantly male veterans who were eligible for long-term dental care within the Department of Veterans Affairs. They ranged in age from 20 years to 80 years (mean 62.9 years). Both HA-coated and non-HA implants were placed by different clinical investigators at each of the research centers, in three of the four jaw regions: 1) maxillary anterior, 2) mandibular anterior, and 3) mandibular posterior.[9] The fourth was the maxillary posterior region, which generally involves poor bone quality; only HA-coated implants were used, making comparisons impossible. In the three jaw regions thus, just mentioned, randomization was used to determine anterior/posterior location of the different implant types (Table 1). The implants were connected with a standardized prosthesis design as specified in the study protocol. These study procedures helped ensure that each implant was subjected to similar functional and environmental conditions. The surgical, restorative,

Table 1.

Implant Types Randomized Within Each Jaw Region (Strata)

Jaw Regions	Implant Design*	Recommended Prosthesis Design
Maxillary anterior	HA-coated screw HA-coated grooved CP-titanium screw	Bar overdenture
Mandibular anterior	Titanium-alloy screw Titanium-alloy basket HA-coated cylinder	Screw-retained hybrid
Mandibular posterior	Titanium-alloy basket HA-coated cylinder	Screw-retained partial

* Spectra system, Core-Vent Corporation, DBA Paragon Company, Encino, CA.

and follow-up data were gathered using standardized forms. Completed forms were sent to the Data Management Center for entry into the main database.

Data Comparisons

A total of up to 20,000 periodontal-type measurements for more than 2,900 implants were made for the following variables: Löe and Silness gingival index (GI),[10] Silness and Löe plaque index (PI),[11] calculus index (CI), suppuration index (SI), probing depth, attachment level, gingival recession, and width of keratinized tissue. To help ensure that the conditions to which the HA-coated and non-HA implants were subjected were as similar as possible, the comparisons of the periodontal-type measurements are reported by each jaw region. Baseline for data comparisons was 3 months post-uncovering.

The data for gingival recession, attachment levels, keratinized tissue, and probing depth measurements were compared using 95% confidence intervals for each follow-up visit. The confidence intervals shown in Figures 1A-D, 3A-D, and 5A-D, for the various evaluation visits, assume independent measurements and do not take into consideration the repeated measurements nature of the data. Figures involving "Trellis plots" would have resulted in numerous points that were connected together, making them impossible to understand. Simple confidence interval plots were therefore utilized in this paper. Statistical testing of the data was also completed using the generalized estimating equations (GEE) method found in SUDAAN statistical procedures.¶ The implant was considered to be the experimental unit. The four aspects—mesial, facial, distal, lingual—of each implant measured, as well as the measures over the 36 months, were all clustered in the unit of analysis.

For GI, PI, CI, and SI, data were analyzed separately. Since the absence of disease is the ultimate objective of any treatment approach, the percentage of implants receiving a score of zero for these indices was used to summarize the differences between HA-coated and non-HA implants. Evaluation criteria for the periodontal indices are shown in Table 2. Comparisons of all aspects of the implant (mesial, facial, distal, and lingual) were similar. For the sake of brevity, only the facial aspect measurements are included in this paper.

Statistical significance represents a conclusion that there is evidence against the null hypothesis set forth in the study protocol—that there is a low probability of getting a result as extreme or more extreme than the one recorded by the study, if the hypothesis is true. Clinical significance for this study was defined as a difference large enough that it would be expected to have implications as to the quality of clinical care that has been provided.[12]

RESULTS

Mandibular Anterior Region

The order of placement for three types of implants were randomized as to position within this jaw region (Table

¶ Research Triangle Institute, Research Triangle Park, NC.

Table 2.

Evaluation Criteria for Periodontal Indices

Periodontal Indices	Score	Evaluation Criteria
Plaque index[11]	0	No plaque on the implant near gingiva.
	1	A light film of plaque on the implant near gingival margin.
	2	Moderate accumulation of plaque near gingival margin.
	3	Abundance of plaque covering much of the implant.
Gingival index[10]	0	Normal gingiva, no inflammation, no discoloration, no bleeding upon probing.
	1	Mild inflammation, slight color change, no bleeding upon probing.
	2	Moderate inflammation, erythema, bleeding on probing.
	3	Severe inflammation, severe erythema and swelling, tendency toward spontaneous hemorrhage and bleeding upon probing.
Calculus index	0	Absence of color.
	1	Supragingival calculus only.
	2	Light, localized subgingival calculus with or without supragingival calculus.
	3	Heavy generalized subgingival calculus.
Suppuration index	0	No suppuration present.
	1	Suppuration present.

1). The types of implants placed were HA-coated cylinder, titanium-alloy screw, and titanium-alloy basket. Recession, probing depth, attachment level, and width of keratinized tissue measurements are compared using the 95% confidence intervals in Figures 1A-D and generalized estimating equation (GEE) methods.

Gingival recession increased slightly, from 2.0 mm (SD = 1.9) for HA-coated implants at baseline to 2.2 mm (SD = 1.6) at 36 months (Fig. 1A), an increase which, while not statistically significant (95% CI), was of clinical interest because of the potential for it to continue beyond the observation period. There was a slight increase in recession for the non-HA implants as well, from 2.3 mm at baseline to 2.5 mm at 36 months. This small difference was, however, statistically significant (95% CI and GEE). While not clinically significant, it is also of clinical interest because of the possibility the trend will continue. Significantly more recession was associated with the use of non-HA implants. The differences between the two implant

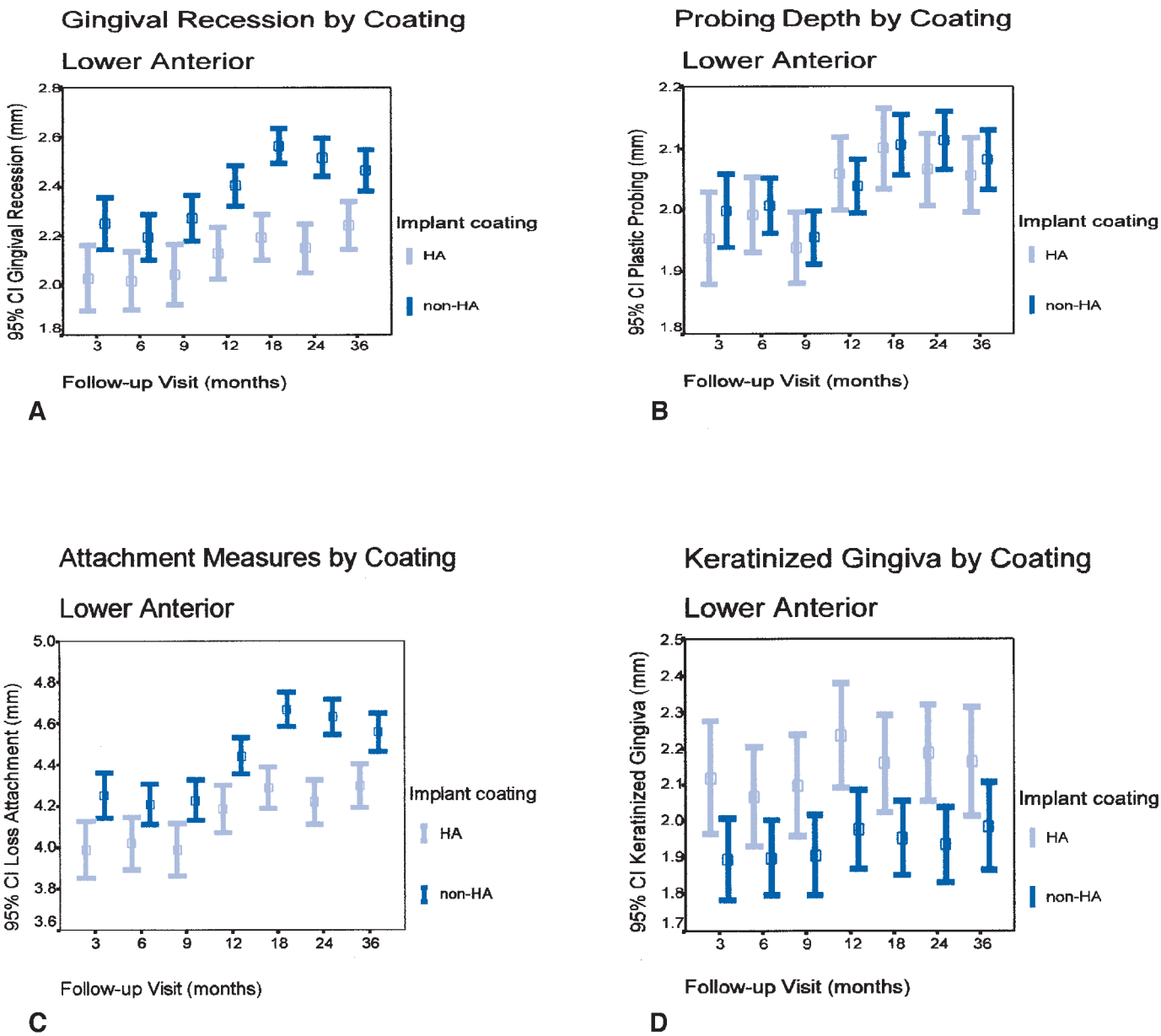

Figure 1.
A. *Gingival recession: HA versus non–HA-coated mandibular anterior implants (95% CI for periodontal-type measures to 36 months).* ***B.*** *Probing depth: HA versus non–HA-coated mandibular anterior implants (95% CI for periodontal-type measures to 36 months).* ***C.*** *Loss of attachment: HA versus non–HA-coated mandibular anterior implants (95% CI for periodontal-type measures to 36 months).* ***D.*** *Keratinized gingiva: HA versus non–HA-coated mandibular anterior implants (95% CI for periodontal-type measures to 36 months).*

types that were evident for the various visits remained small but were statistically significant (GEE). The true clinical significance of these small differences remains questionable. The statistical conclusion concerning the difference in recession measurements for these two implant types would have resulted regardless of whether or not the 95% confidence intervals or the more complex GEE analyses were used.

The probing depth recorded at each visit is shown in Figure 1B. This measurement increased from 2.0 mm at 3 months to only 2.1 mm at 36 months for the HA-coated implants, which was a statistically significant increase (95% CI, GEE). The non-HA implants showed nearly identical changes. The probing depths recorded beyond the 12- to 18-month visit were significantly different (95% CI, GEE) from those recorded from 3 to 12 months for both the HA-coated and non-HA implant types. This increase in probing depth is of concern, for it may indicate a worsening of periodontal health.

The relative attachment loss for HA-coated implants was generally smaller than that of the non-HA implants at each visit (Fig. 1C). For HA-coated implants, the attachment loss progressed during clinical function, from 4.0 mm at 3 months to 4.3 mm at 36 months. Attachment loss for non-HA implants during this same period increased from 4.3 mm at 3 months to 4.6 mm at 36 months. The increases for both implant types were significant (95% CI, GEE) but of limited clinical significance during the 36-month observation period. Attachment loss for non-HA implants was statistically significantly larger than that of HA-coated implants at all follow-up visits.

The amount of keratinized tissue around HA-coated implants at each evaluation visit was slightly wider than that found around the non–HA-coated implants; however, this difference was not statistically significant (Fig. 1D). The width of keratinized tissues around HA-coated implants ranged from 2.1 mm at 3 months to only 2.2 at 36 months, which was similar to the range of 1.9 mm at 3 months to 2.0 mm at 36 months for non-HA implants. The width of these tissues remained relatively consistent over time, and the differences between the implant types were significant (GEE).

The periodontal indices for the two implant types were recorded for all aspects of the implant. For brevity, the differences between the implants are summarized and compared by plotting only the percentage of implants having a recorded index of zero for the facial aspect of the implant (Fig. 2A-D). Comparisons of other aspects were similar to those for the facial aspect of the implant and, for the sake of brevity, are not included in this paper.

Percentages of implants with a GI = 0 are remarkably similar for both HA-coated and non-HA implant types (Fig. 2A) for each visit. The PI (Fig. 2B) for the two implants was also similar. The percentage of HA-coated implants with CI = 0 (Fig. 2C) over all visits was significantly greater than the non-HA implants (GEE). Incidents of suppuration were examined for the two implant types for only the facial surface. While there was a statistically significant difference (GEE), the differences in the SI would not be considered clinically significant for the 36-month observation period (Fig. 2D).

Mandibular Posterior Region

Implant designs used in this jaw region included HA-coated cylinders and titanium-alloy baskets (Table 1). Relative gingival recession for HA-coated implants decreased from 1.6 mm at 3 months to 1.2 mm at 36 months, which represented a statistically significant (95% CI) change (Fig. 3A). For non-HA implants, recession also decreased from 1.6 mm at 3 months to 1.3 mm at 36 months, but this change was not significant. The recession measures for HA implants were consistently less than those associated with the non-HA implant. The small differences found over all visits were significant (95% CI, GEE). The probing depth measurements for both implant types increased significantly (95% CI, GEE) over time (Fig. 3B) from 2.1 mm at 3 months to 2.4 mm at 36 months. The HA-coated implants had small but significantly greater (95% CI, GEE) probing depths than the non-HA implants over all visits. Relative attachment levels for both HA-coated and non-HA implants decreased initially between the 6- to 12-month visits before increasing again (Fig. 3C). The levels varied from 3.5 mm to 3.8 mm for both HA-coated and non-HA implants, and these changes were not significantly different. The width of keratinized tissue around both HA-coated and non-HA implants decreased significantly (95% CI, GEE) over time (Fig. 3D). There was not a significant difference between the loss of keratinized tissue around the HA-coated implants when compared to the non-HA implants. While not significant (but of clinical interest) at this point, the data suggest that the tissue width associated with non-HA implants decreased more rapidly than that around HA implants.

Data related to the periodontal indices are summarized for the facial surface in Figures 4A-D for each implant type and each evaluation visit. The percentage of both implants recorded as having no evidence of gingival inflammation (GI = 0) is not significantly different for the two implant types at each visit (Fig. 4A). The non-HA implants without evidence of differences in plaque accumulation (PI = 0), for the two implant types, were significantly different (GEE) for all aspects of the implant (Fig. 4B); however, the differences were small and would not be considered clinically significant. When comparing the CI for each implant type, the non-HA implants had a slightly but statistically higher (GEE) incidence of calculus than the HA-coated implants (Fig. 4C). The percentage of implants with

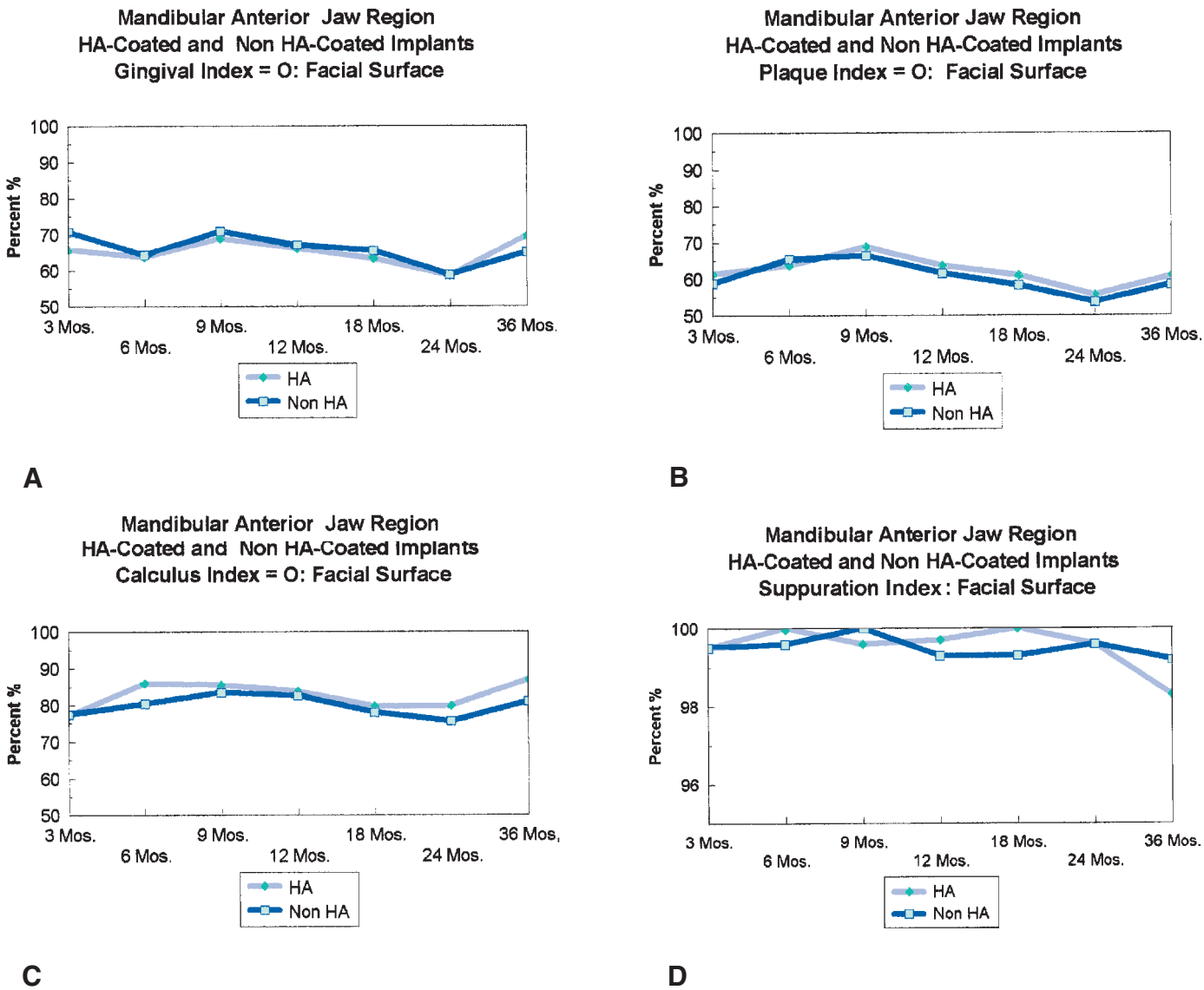

Figure 2.
A. *Mandibular anterior jaw region: percentage of HA and non-HA implants with no clinical evidence of gingivitis (GI = 0). No significant difference (P >0.13, GEE).* ***B.*** *Percentage of HA and non-HA implants with no clinical evidence of plaque formation (PI = 0). No significant difference (P >0.13, GEE).* ***C.*** *Percentage of HA and non-HA implants without evidence of calculus accumulation (CI = 0). Significant difference (P <0.001, GEE).* ***D.*** *Percentage of HA and non-HA implants without evidence of suppuration (SI = 0). Significant difference (P <0.001, GEE).*

suppuration recorded at certain visits varied slightly (Fig. 4D) for the facial surface, but this variation was not statistically significant for the two implants.

Maxillary Anterior Region

Implants randomized within this jaw region included HA-coated grooved, HA-coated screw, and CP-titanium screw designs (Table 1). Data for the implants in this jaw region are summarized in Figures 5A-D. Relative gingival recession for both implant types decreased over time (Fig. 5A). Recession for HA-coated implants was 1.9 mm at 3 months, decreasing to 1.2 mm at 36 months. Recession measurements for non-HA implants were slightly lower at 3 months (1.6 mm), and they decreased even more (1.0 mm) at 36 months. For the earlier visits, there were no significant differences observed when changes from baseline were considered; however, the decrease in recession over time was statistically significant (95% CI, GEE) for both the HA-coated and non-HA implants. The differences in the recession measures between HA-coated and non-HA implants when compared at each visit were not significant (95% CI). Probing depth measurements increased significantly over time for

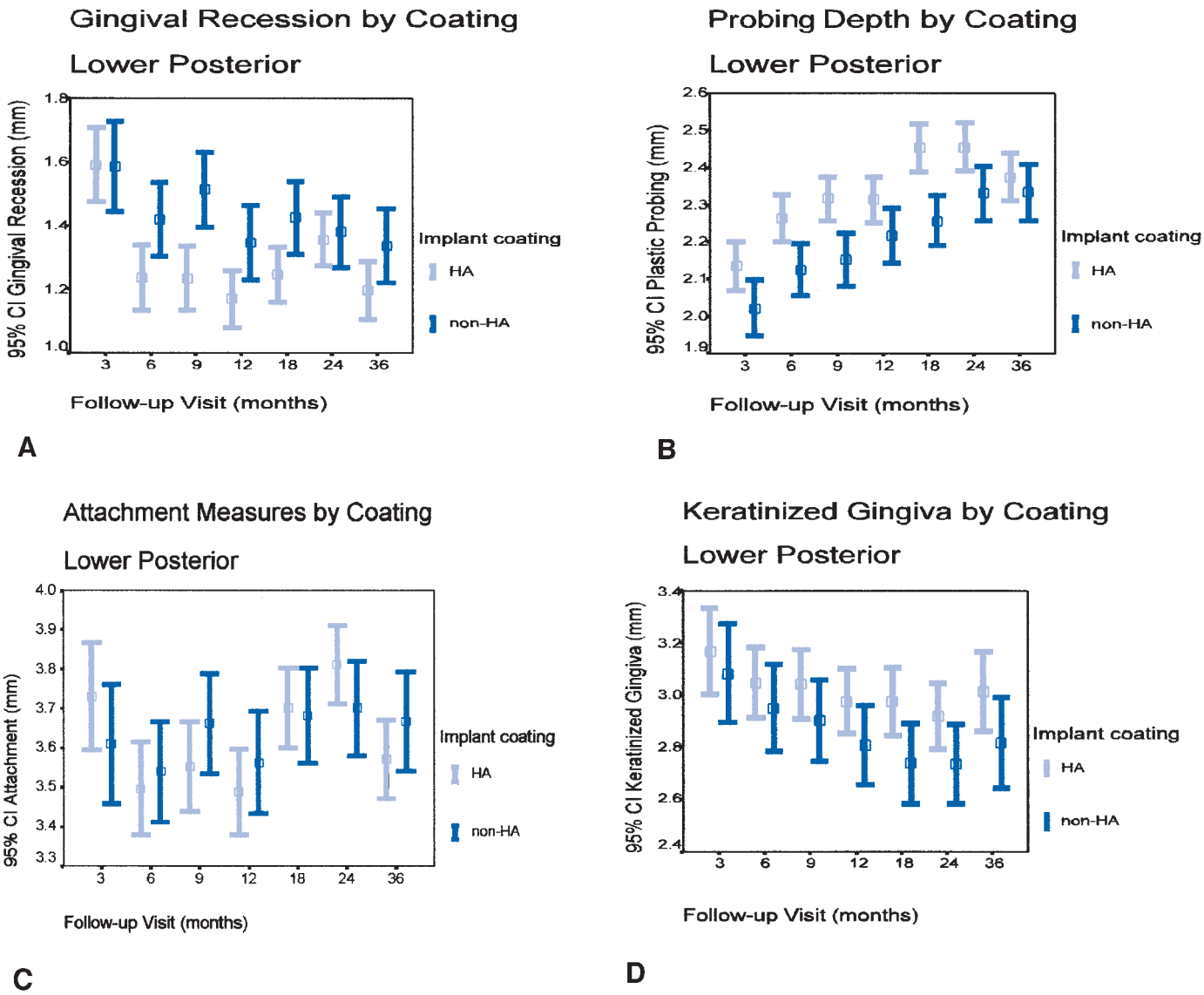

Figure 3.
A. *Gingival recession: HA versus non–HA-coated mandibular posterior implants (95% CI for periodontal-type measures to 36 months).* ***B.*** *Probing depth: HA versus non–HA-coated mandibular posterior implants (95% CI for periodontal-type measures to 36 months).* ***C.*** *Loss of attachment: HA versus non–HA-coated mandibular posterior implants (95% CI for periodontal-type measures to 36 months).* ***D.*** *Keratinized gingiva: HA versus non–HA-coated mandibular posterior implants (95% CI for periodontal-type measures to 36 months).*

both implant types (Fig. 5B), which is of clinical concern. Probing depth for HA-coated implants increased from 2.5 mm at 3 months to 3.1 mm at 36 months, while the non-HA implant probing depth measurements increased from 2.4 mm at 3 months to 3.0 mm at 36 months. Both implant types showed significant (95% CI) increases in probing depths over the 36-month period. These measurements between the two implant types were not significantly different for each follow-up visit. Relative attachment levels varied somewhat toward increased measurements (Fig. 5C). There was a generalized loss of attachment (increase in measures) over time for both implants, which was not statistically significant. Attachment levels at 3 months for HA-coated implants were 4.4 mm, which increased to 4.5 mm at 9 months and then decreased to 4.2 mm at 36 months. Attachment losses for non-HA implants were significantly (95% CI) smaller than for HA-coated implants for all visits. The width of keratinized tissues remained relatively constant over time (Fig. 5D) for the two implant types, with no significant difference for either implant type or between the two types at each visit (95% CI). Overall, however, there was a significant difference (GEE) in the width of the keratinized tissues between the two implants, which would not likely be considered clinically significant for the 36-month observation period.

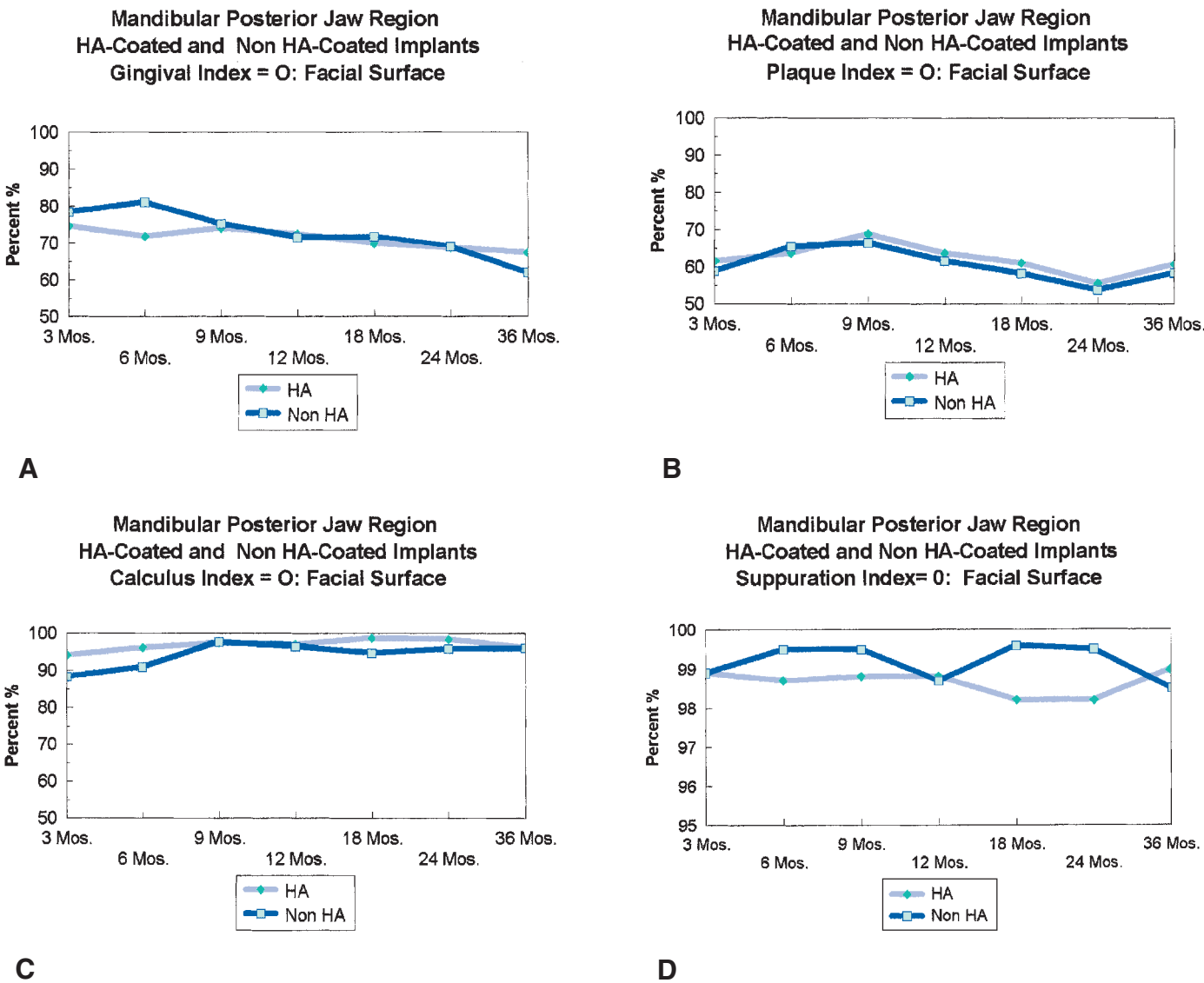

Figure 4.
A. *Mandibular posterior jaw region: percentage of HA-coated and non-HA implants without evidence of inflammation (GI = 0). No significant difference (P >0.13, GEE).* ***B.*** *Percentage of HA-coated and non-HA implants without evidence of plaque formation (PI = 0). No significant difference (P <0.04, GEE).* ***C.*** *Percentage of HA-coated and non-HA implants without calculus (CI = 0). Significant difference (P <0.001, GEE).* ***D.*** *Percentage of HA-coated and non-HA implants without evidence of suppuration (SI = 0). No significant difference (P >0.12, GEE).*

Changes in the periodontal indices are shown for the facial surface of both implant types at each evaluation (Fig. 6A-D). The percentage of implants free of gingivitis (GI = 0) appears to be slightly greater for non-HA implants, but this difference was not significant (95% CI, GEE). There appears to be a decrease in the percentage of implants with GI = 0, indicating a generalized trend toward a very slight increase in gingivitis over time (Fig. 6A); however, this decrease was not significant during the 36 months of follow-up. The PI is shown for the facial surface of each implant type at each evaluation visit (Fig. 6B). The data for the PI suggest a slight decrease in the percentage of plaque-free implants for both implant types over time, which was not found to be significant for the 36-month evaluation period. No major difference in plaque accumulation was evident between the two types. Data related to the calculus index show similar patterns (Fig. 6C) for the two implant types over time. For the facial aspect, there was a significantly (GEE) larger percentage of HA-coated implants with PI = 0 than non-HA implants. Incidents of suppuration associated with the facial surfaces of both HA-coated and non-HA implants remained extremely small and were neither statistically nor clinically significant (Fig. 6D).

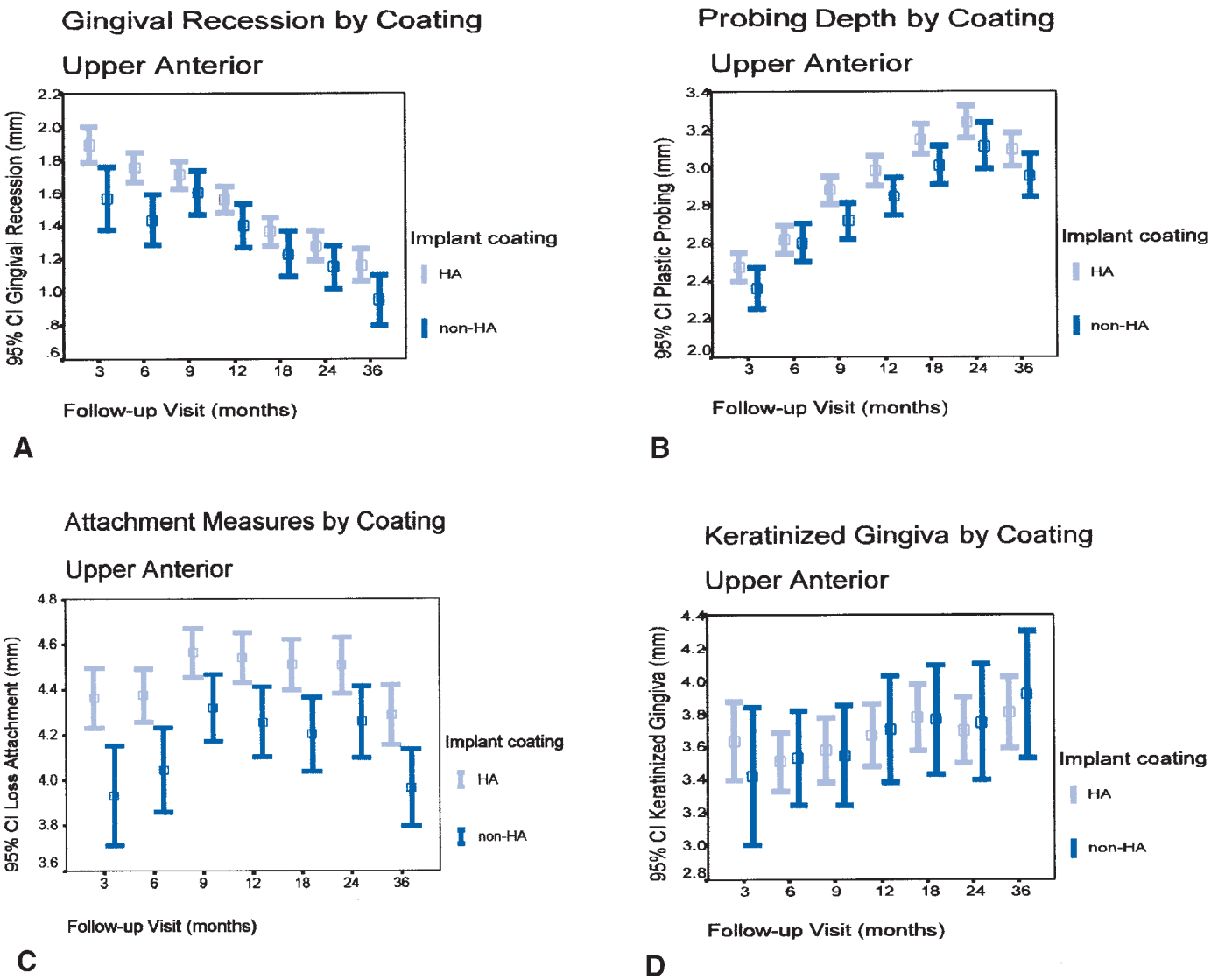

Figure 5.
A. *Gingival recession: HA versus non–HA-coated maxillary anterior implants (95% CI for periodontal-type measures to 36 months).* ***B.*** *Probing depth: HA versus non–HA-coated maxillary anterior implants (95% CI for periodontal-type measures to 36 months).* ***C.*** *Loss of attachment: HA versus non–HA-coated maxillary anterior implants (95% CI for periodontal-type measures to 36 months).* ***D.*** *Keratinized gingiva: HA versus non–HA-coated maxillary anterior implants (95% CI for periodontal-type measures to 36 months).*

DISCUSSION

Dentistry is constantly seeking new ways to improve the quality of patient care. The existing knowledge base associated with endosseous dental implants is replete with commercialism, subjective data, objective data, and is in a constant state of change as new information is reported. With every product used in dentistry, there is a natural learning curve as clinicians familiarize themselves with the product and test the limits of its application.[13]

Titanium implants have gained widespread acceptance since their introduction. The bone is believed to attach to the titanium implant by means of a complex interaction involving the titanium-oxide and extracellular matrix tissues [14,15] along with macro- and microinterlocking.[16] It soon became evident that under certain clinical conditions and clinical prosthetic applications, the survival of titanium implants was problematic. To improve long-term clinical success, the implant surfaces have been altered by adding rough coatings,[17-19] acid etching,[20,21] grit blasting,[22,23] and grit blasting plus acid etching.[24,25]

Today, one of the most controversial topics in implant dentistry is the use of HA-coated implants. Hydroxyapatite is a calcium phosphate that is part of natural teeth and bone. It was first used for dental implants in 1984[1] and is reported to provide a bioactive coating that bonds directly to bone.[26,27] While

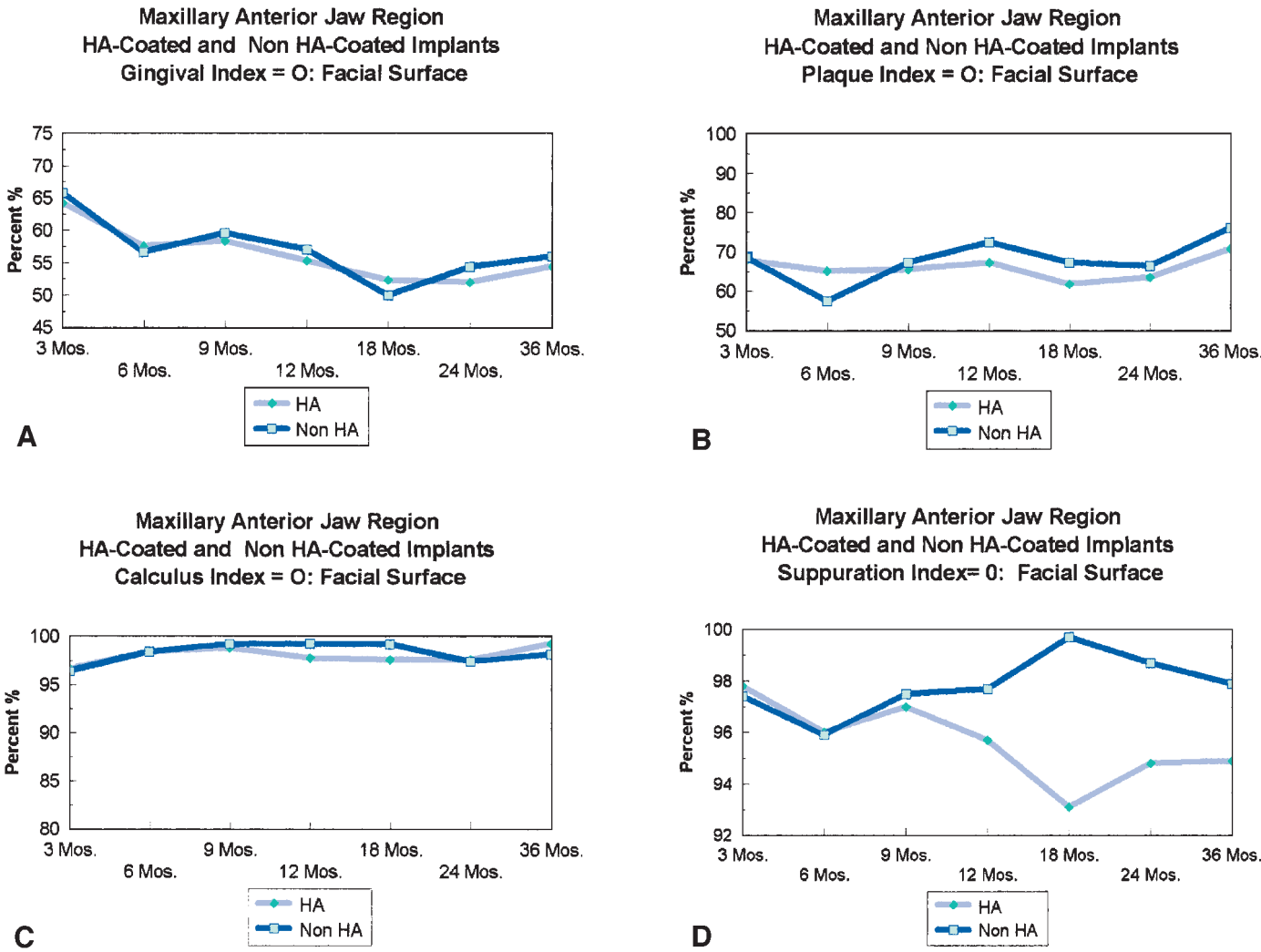

Figure 6.
A. *Maxillary anterior jaw region: percentage of HA-coated and non-HA implants without evidence of gingivitis (GI = 0). No significant difference (P >0.23, GEE).* ***B.*** *Percentage of HA-coated and non-HA implants without evidence of plaque accumulation (PI = 0). No significant difference (P >0.63, GEE).* ***C.*** *Percentage of HA-coated and non-HA implants without calculus accumulation (CI = 0). Significant difference (P <0.009, GEE).* ***D.*** *Percentage of HA-coated and non-HA implants without evidence of suppuration (SI = 0). No significant difference (P >0.41, GEE).*

early formulations of HA coatings may not have provided the desired clinical performance, natural evolutionary pressures dictated that they be modified to develop improved clinical performance, and then be tested against the industry standard—non-HA implants.

Rarely do commercially sponsored studies focus on comparing the performance of more than one implant design. When they do, the sponsor may exert some influence on the selection of the implant designs. Even more rare is the study design that uses two different implant types, such as HA-coated and non-HA implants, that are placed in the same jaw regions and subjected to similar conditions during the entire period of the clinical study. Most researchers will agree that one of the best experimental designs to use when trying to compare two different items is a paired comparison. Such a design would subject the different implants to identical conditions, at least to the extent that this is possible in a clinical environment with all of the confounding variables that exist. To further limit the ability to make meaningful comparisons of clinical performance of different implant types, periodontal-type measurements are generally not reported in such studies and, when they are, the sample size is small.

There are other obstacles that prevent comparisons of HA-coated and non-HA implants as they might apply to the majority of dental offices. Some clinical studies supported by implant manufacturers seem to involve only highly skilled and experienced dentists who provide treatment to carefully selected patients—good

health histories, large residual edentulous ridges, etc.—under ideal conditions in specific geographic regions. A search of the literature shows that poor data outcomes for a specific implant type either do not exist or are infrequently reported for a variety of reasons. In everyday life, dentists with different levels of training, skills, experience, and treatment philosophies provide implant treatment to patients who present a wide variety of needs for the best dental rehabilitation that dentistry can provide. Those patients seeking implant treatment come from various backgrounds and geographic regions and have a wide variety of personal characteristics and physical conditions.

One of the major criticisms associated with comparing the clinical performance of HA-coated and non-HA implants has been the differences in the manner in which studies were designed and conducted. To counter this criticism, the DICRG placed both implant types in the same jaw regions, by the same group of dentists, in the same patients, restored with the same prosthesis design to keep stresses during clinical function as similar as possible. Furthermore, the DICRG maintained total data independence from external influences by blinding all professional participants and representatives of any commercial company as to early data trends and final outcomes.

Recent papers from the prospective clinical study designed and conducted by the DICRG have reported on the superior short-term (36-month) performance of HA-coated implants.[28,29] HA-coated implants have been found to provide in each of the DICRG research centers a more rapid osseointegration.[29] They have also shown superior performance at each stage of treatment to 36 months,[29] in smokers,[29] in poor bone quality,[29] in the hands of less experienced surgeons,[29] in patients with moderate health problems,[29] in cases where preoperative antibiotics were not used,[29] in the presence of slight mobility at placement,[29,30] and in each jaw region.[29]

The data in this study provide continuing scientific evidence that when HA-coated implants are compared to non-HA implants, their performance is at least equal to the non-HA implant when periodontal-type responses are considered. Despite the similarities of the conditions that existed in the DICRG study with those in the average dental office, caution must be used in reviewing the data contained within this paper. The only major difference that may exist between the conditions in the average dental office and that of the DICRG is that all patients were followed closely and were maintained in optimal oral health at 3- to 6-month recall visits. This was a condition that was required by the Human Studies Committee at all DVA research centers. For these results to be fully applicable to the average dental office, the private patients must be maintained in a similar manner.

CONCLUSION

The data presented in this paper indicate that there is no clinically significant difference between periodontal-type responses of supporting hard and soft tissues surrounding HA-coated or non–HA-coated implants for a period of 3 to 36 months post-uncovering.

REFERENCES

1. Golec TS, Krauser JT. Long-term retrospective studies on hydroxyapatite-coated endosteal and subperiosteal implants. *Dent Clin North Am* 1992;36:39-65.
2. Johnson B. HA coated implants: Long-term consequences. *J Calif Dent Assoc* 1992;20:33-41.
3. Albrektsson T, Sennerby L. State of the art in oral implants. *J Clin Periodontol* 1991;18:474-481.
4. Biesbrock AR, Edgerton M. Evaluation of the clinical predictability of hydroxyapatite-coated endosseous dental implants: A review of the literature. *Int J Oral Maxillofac Implants* 1995;10:712-720.
5. Kay JF. Calcium phosphate coatings for dental implants: Current status and future potential. *Dent Clin North Am* 1992;36:1-18.
6. Kim Y, LeGeros J, Le Geros R. Characterization of commercial HA-coated dental implants. *J Dent Res* 1994;73 (Spec. Issue):137(Abstr. 287).
7. LeGeros R, Craig R. Strategies to affect bone remodeling: Osteointegration. *J Bone Miner Res* 1993;8:S583-S596.
8. Nery E, LeGeros R, Lynch K, Lee K. Tissue response to biphasic calcium phosphate ceramic with different ratios of HA/beta TCP in periodontal osseous defects. *J Periodontol* 1992;63:729-735.
9. Morris HF, Ochi S. The influence of implant design, application, and site on clinical performance and crestal bone: A multicenter, multidisciplinary clinical study. *Implant Dent* 1992;1:49-55.
10. Löe H, Silness J. Periodontal disease in pregnancy. I. Prevalence and severity. *Acta Odontol Scand* 1963;21: 533-551.
11. Silness J, Löe H. Periodontal disease in pregnancy. II. Correlation between oral hygiene and periodontal condition. *Acta Odontol Scand* 1964;22:121-135.
12. Lang TA, Secic M. Differences between clinical and statistical significance. In: Huth EJ, ed. *How to Report Statistics in Medicine*. Philadelphia: American College of Physicians; 1997:xiii.
13. Block MS, Kent JN. Long-term follow-up on hydroxylapatite-coated cylindrical dental implants: A comparison between developmental and recent periods. *J Oral Maxillofac Surg* 1994;52:937-943.
14. Kasemo B, Lausmaa J. Aspects of surface physics on titanium implants. *Swed Dent J* 1985;28(Suppl.):19-36.
15. Stanford CM, Keller JC. The concept of osseointegration and bone matrix expression. *Crit Rev Oral Biol Med* 1991;2:83-101.
16. Brunski JB. Biomechanics of oral implants: Future research directions. *J Dent Educ* 1988;52:775-787.
17. Buser D, Schenk RK, Steinemann S, Fiorellini JP, Fox CH, Stich H. Influence of surface characteristics on bone integration of titanium implants. A histomorphometric study in miniature pigs. *J Biomed Mater Res* 1991;25:889-902.
18. Deporter DA, Watson PA, Pilliar RM, et al. A prospective clinical study in humans of an endosseous dental implant partially covered with a powder-sintered porous coating: 3-4 year results. *Int J Oral Maxillofac Implants* 1996;11:87-95.
19. Schroeder A, Van Der Zypen E, Stich H, Sutter F. The

reactions of bone, connective tissue, and epithelium to endosteal implants with titanium-sprayed surfaces. *J Maxillofac Surg* 1981;9:15-25.
20. Klokkevold P, Nishimure R, Adachi M, Caputo A. Osseointegration enhanced by chemical etching of the titanium surface. *Clin Oral Implants Res* 1997;8:442-447.
21. Sullivan DY, Sherwood RL, Mai TN. Preliminary results of a multicenter study evaluating a chemically enhanced surface for machined commercially pure titanium implants. *J Prosthet Dent* 1997;78:379-386.
22. Wennerberg A, Hallgren C, Johansson C, Danelli A. A histomorphometric evaluation of screw-shaped implants each prepared with two surfaces. *Clin Oral Implants Res* 1998;9:11-19.
23. Ericsson I, Johansson CB, Bystedt H, Norton MR. A histomorphometric evaluation of bone-to-implant contact on machine-prepared and roughened titanium dental implants. A pilot study in the dog. *Clin Oral Implants Res* 1994;5:202-206.
24. Wong M, Eulenberger R, Schenk R, Hunziker E. Effect of surface topology on the osseointegration of implant materials on trabecular bone. *J Biomed Mater Res* 1995;29: 1567-1575.
25. Pebé P, Barbot R, Trinidad J, et al. Countertorque testing and histomorphometric analysis of various implant surfaces in canines: A pilot study. *Implant Dent* 1997; 6:259-265.
26. Block MS, Kent JN, Finger IM. Evaluation of hydroxylapatite coated titanium dental implants in dogs. *J Oral Maxillofac Surg* 1987;45:601-607.
27. Meffert RM, Block MS, Kent JN. What is osseointegration? *Int J Periodontics Restorative Dent* 1987;7(4):9-21.
28. Morris HF, Lambert PM, Ochi S. The influence of tobacco use on endosseous implant failures. *Oral Maxillofac Surg Clin North Am* 1998;10:255-274.
29. Morris HF, Ochi S. HA-coated implants: A case for their use. *J Oral Maxillofac Surg* 1998;56:1303-1311.
30. Orenstein IH, Tarnow DP, Morris HF, Ochi S. Factors affecting implant mobility at placement and integration of mobile implants at uncovering. *J Periodontol* 1998; 69:1404-1412.

Accepted for publication August 1, 2000.